

65302

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6002-10-12

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
Sanford T. Colb & Co.
P.O. Box 2273
76122 Rehovot
Israel

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	
Applicant's or agent's file reference 65302	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/IL 08/00687	International filing date (day/month/year) 20 May 2008 (20.05.2008)
Applicant SMART MEDICAL SYSTEMS LTD.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1460, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
Sanford T. Colb & Co.
P.O. Box 2273
76122 Rehovot
Israel

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

09 JUL 2009

Applicant's or agent's file reference
65302

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/IL 08/00687

International filing date
(day/month/year) **20 May 2008 (20.05.2008)**

Applicant **SMART MEDICAL SYSTEMS LTD.**

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 8270

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSF: 571-272-7774

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 65302	FOR FURTHER ACTION <div style="text-align: right; font-size: small;">see Form PCT/ISA/220 as well as, where applicable, item 5 below.</div>	
International application No. PCT/IL 08/00687	International filing date (<i>day/month/year</i>) 20 May 2008 (20.05.2008)	(Earliest) Priority Date (<i>day/month/year</i>) 21 May 2007 (21.05.2007)
Applicant SMART MEDICAL SYSTEMS LTD.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☒ Certain claims were found unsearchable (see Box No. II).

3. ☒ Unity of invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1A
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 08/00687

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☒ Claims Nos.: 6-9, 15-18 and 22
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
— see continuation sheet —

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5, 10-14, 19-21, 29

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☒ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 08/00687

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 25/10 (2009.01)

USPC - 604/528

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61M 25/10 (2009.01)

USPC - 604/528

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

A61M 25/00, 25/01 (2009.01)

604/284, 915, 916, 523

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST(USPT,PGPB,EPAB,JPAB); Google Scholar;

Search Terms Used: catheter, bend, flex, deflect, guidewire, steer, balloon, tapered, bowing, endoscope

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,951,554 B2 (JOHANSEN et al.) 04 October 2005 (04.10.2005) Entire document, especially col 2, ln 20-40, col 2, ln 67 - col 3, ln 5, col 5, ln 62 - col 6, ln 11 and FIGS. 1-4.	1, 3, 4/(1,3), 5/(1,3), 10, 12, 13/(10,12) and 14/(10,12)
Y		19-21 and 28
X	US 2005/0273021 A1 (BURGERMEISTER) 08 December 2005 (08.12.2005) Entire document, especially para[0003], para[0018], para[0022]-[0024], para[0029] and FIGS. 1-2.	1, 2, 4/(2), 5/(2), 10, 11, 13/(11) and 14/(11)
Y	WO 2004/101059 A1 (KENNEDY) 25 November 2004 (25.11.2004) p4, ln 3-12 and FIGS. 5.	19-21
Y	US 2006/0241345 A1 (OISHI et al.) 26 October 2006 (26.10.2006) para[0042] and FIG. 3.	28

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

19 May 2009 (19.05.2009)

Date of mailing of the international search report

09 JUL 2009

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-273-4800

PCT OSP: 571-273-7774

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 08/00687

Box No III: Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

In order for more than one species to be examined, the appropriate examination fees must be paid.

The Species are as follows:

Group I: corresponding to a catheter having a lumen, a flexible or bendable portion and a balloon

Group II: corresponding to a catheter having a tapered balloon

Group III: corresponding to an external tube for a catheter or endoscope having liquid communication ports

The claims are deemed to correspond to the species listed above in the following manner

Group I: claims 1-5, 10-14, 19-21, 29

Group II: claims 23, 24, 29

Group III: claims 25-28

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a flexible or bendable portion, the special technical feature of Group II is a tapered balloon and the special technical feature of Group III is a liquid communication port.

Neither of these technical features is common to the other group nor do they correspond to a special technical feature in the other groups.

The following claim is generic to groups I and II: 29

This generic claim does not avoid the prior art, as evidenced by US 2007/0016165 A1 to VON CEPEN which teaches a catheter having variable stiffness along its length and a balloon which may be tapered (para [0012], [0014], [0031]).

Thus, unity of invention is lacking under PCT Rule 13 because the groups do not share the same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To: Sanford T. Coib & Co. P.O. Box 2273 76122 Rehovot Israel		<div style="text-align: right; font-size: 1.2em; font-weight: bold;">09 JUL 2009</div>	
Applicant's or agent's file reference 65302		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/IL 08/00687	International filing date (<i>day/month/year</i>) 20 May 2008 (20.05.2008)	Priority date (<i>day/month/year</i>) 21 May 2007 (21.05.2007)	
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61M 25/10 (2009.01) USPC - 604/528			
Applicant SMART MEDICAL SYSTEMS LTD.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 19 May 2009 (19.05.2009)	Authorized officer: Lee W. Young <small>PCT Helpdesk: 571-272-4300 PCT QSP: 571-272-7774</small>
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 08/00687

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 08/00687

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 6-9, 15-18 and 22

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international search (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 6-9, 15-18, 22 are so unclear that no meaningful opinion could be formed (*specify*):
claims 6-9, 15-18, 22 are improper multiple dependent claims not in compliance with the second and third sentences of PCT Rule 6.4(a)

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for said claims Nos. 6-9, 15-18 and 22

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.I(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL 08/00687

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons:

In order for more than one species to be examined, the appropriate examination fees must be paid.

The Species are as follows:

Group I: corresponding to a catheter having a lumen, a flexible or bandable portion and a balloon

Group II: corresponding to a catheter having a tapered balloon

Group III: corresponding to an external tube for a catheter or endoscope having liquid communication ports

The claims are deemed to correspond to the species listed above in the following manner:

Group I: claims 1-5, 10-14, 19-21, 29

Group II: claims 23, 24, 29

Group III: claims 25-28

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a flexible or bandable portion, the special technical feature of Group II is a tapered balloon and the special technical feature of Group III is a liquid communication port.

Neither of these technical features is common to the other group nor do they correspond to a special technical feature in the other groups.

The following claim is generic to groups I and II: 29

This generic claim does not avoid the prior art, as evidenced by US 2007/0016165 A1 to VON OEPEN which teaches a catheter having variable stiffness along its length and a balloon which may be tapered (para [0012], [0014], [0031]).

Thus, unity of invention is lacking under PCT Rule 13 because the groups do not share the same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☐ all parts
- ☒ the parts relating to claims Nos. 1-5, 10-14, 19-21 and 29

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/IL 08/00687

Box No. V Reasoned statement under Rule 43bis.3(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	19-21 and 29	YES
	Claims	1-5 and 10-14	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-5, 10-14, 19-21 and 29	NO
Industrial applicability (IA)	Claims	1-5, 10-14, 19-21 and 29	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 3, 4/(1,3), 5/(1,3), 10, 12, 13/(10,12) and 14/(10,12) lack novelty under PCT Article 33(2) as being anticipated by US 6,951,554 B2 to Johansen et al. (hereinafter: Johansen).

As per claim 1, Johansen describes a catheter (10, FIG. 3) comprising:
a tube (18, FIG. 1) having at least one lumen (17, FIG. 1; col 2, ln 38-40);
at least one elongate element (14/64/62, FIG. 2; col 2, ln 20-25), said at least one elongate element having a bendable portion (64) at a predetermined bendable portion location therealong forward of a distal end of said tube (FIGS. 2-4); and
at least one selectively inflatable balloon (76, FIG. 4) communicating with at least one of said at least one lumen (col 2, ln 67- col 3, ln 5),
said at least one selectively inflatable balloon having a forward end (distal end of 76, FIG. 4) and a rearward end (proximal end of 76, FIG. 4), said rearward end of said balloon being located rearwardly of said predetermined bendable portion location (FIG. 4).

As per claim 3, Johansen describes the catheter according to claim 1 and wherein said forward end of said balloon is located forwardly of said predetermined bendable portion location (FIG. 4).

As per claim 4/(1,3), Johansen describes the catheter according to any of claims (1,3) and also comprising a steering element (92/62, FIG. 2) coupled to said elongate element (14) forwardly of said predetermined bendable portion location (col 5, ln 62 - col 6, ln 11).

As per claim 5/(1,3), Johansen describes the catheter according to claim 4/(1,3) and wherein said steering element is manipulatable by an operator for steering of said catheter (col 5, ln 62 - col 6, ln 11).

As per claim 10, Johansen describes a catheter (10, FIG. 3) comprising:
a tube (14/64/62, FIG. 2; col 2, ln 20-25) having at least one lumen (17, FIG. 1; col 2, ln 38-40) and having a bendable portion (64) at a predetermined bendable portion location therealong (FIGS. 2-4); and
at least one selectively inflatable balloon (76, FIG. 4) communicating with at least one of said at least one lumen (col 2, ln 67- col 3, ln 5),
said at least one selectively inflatable balloon having a forward end (distal end of 76, FIG. 4) and a rearward end (proximal end of 76, FIG. 4), said rearward end of said balloon being located rearwardly of said predetermined bendable portion location (FIG. 4).

As per claim 12, Johansen describes the catheter according to claim 1 and wherein said forward end of said balloon is located forwardly of said predetermined bendable portion location (FIG. 4).

As per claim 13/(10,12), Johansen describes the catheter according to any of claims (10,12) and also comprising a steering element (92/62, FIG. 2) coupled to said elongate element (14) forwardly of said predetermined bendable portion location (col 5, ln 62 - col 6, ln 11).

As per claim 14/(10,12), Johansen describes the catheter according to claim 13/(10,12) and wherein said steering element is manipulatable by an operator for steering of said catheter (col 5, ln 62 - col 6, ln 11).

-----Please See Continuation Sheet-----

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/L 08/00687

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V.2. Citations and explanations-----

Claims 1, 2, 4/(2), 5/(2), 10, 11, 13/(11) and 14/(11) lack novelty under PCT Article 33(2) as being anticipated by US 2005/0273021 A1 (Burgermeister).

As per claim 1, Burgermeister describes a catheter (para[0003]; FIG. 1) comprising:
a tube (27, FIG. 2) having at least one lumen (FIG. 2);
at least one elongate element (20, FIG. 1; para[0018]), said at least one elongate element having a bendable portion (34, FIG. 2; para[0022]) at a predetermined bendable portion location therealong forward of a distal end of said tube (FIG. 2); and
at least one selectively inflatable balloon (29) communicating with at least one of said at least one lumen, said at least one selectively inflatable balloon having a forward (distal end FIG. 2) end and a rearward end (proximal end FIG. 2), said rearward end of said balloon being located rearwardly of said predetermined bendable portion location (FIG. 2).

As per claim 2, Burgermeister describes the catheter according to claim 1 and wherein said forward end of said balloon is located rearwardly of said predetermined bendable portion location (FIG. 2).

As per claim 4/(2), Burgermeister describes the catheter according to claim (2), also comprising a steering element (24, FIG. 1; para[0022]-[0024]) coupled to said elongate element (34) forwardly of said predetermined bendable portion location (22, FIG. 2; para[0023]).

As per claim 5/(2), Burgermeister describes the catheter according to claim 4/(2), wherein said steering element is manipulatable by an operator for steering of said catheter (para[0029]).

As per claim 10, Burgermeister describes a catheter (para[0003]; FIG. 1) comprising:
a tube (20/27, FIG. 2) having at least one lumen and having a bendable portion (34, FIG. 2; para[0022]) at a predetermined bendable portion location therealong (FIG. 2); and
at least one selectively inflatable balloon (29) communicating with at least one of said at least one lumen, said at least one selectively inflatable balloon having a forward (distal end FIG. 2) end and a rearward end (proximal end FIG. 2), said rearward end of said balloon being located rearwardly of said predetermined bendable portion location (FIG. 2).

As per claim 11, Burgermeister describes the catheter according to claim 10 and wherein said forward end of said balloon is located rearwardly of said predetermined bendable portion location (FIG. 2).

As per claim 13/(11), Burgermeister describes the catheter according to claim (11), also comprising a steering element (24, FIG. 1; para[0022]-[0024]) coupled to said elongate element (34) forwardly of said predetermined bendable portion location (22, FIG. 2; para[0023]).

As per claim 14/(11), Burgermeister describes the catheter according to claim 13/(11), wherein said steering element is manipulatable by an operator for steering of said catheter (para[0029]).

Claims 19-21 lack an inventive step under PCT Article 33(3) as being obvious over Johansen in view of WO 2004/101059 A1 to (Kennedy).

As per claim 19, Johansen describes a catheter (10, FIG. 3) comprising:
a tube (18, FIG. 1) having at least one lumen (17, FIG. 1; col 2, in 38-40);
at least one elongate element (14/64/62, FIG. 2; col 2, in 20-25), which a distal end of said at least one elongate element (62, FIG. 2) extends beyond said distal end of said tube (cap at 66) by a fixed amount (FIG. 2);
and at least one selectively inflatable balloon (76, FIG. 4) communicating with at least one of said at least one lumen (col 2, in 67- col 3, in 5), said at least one selectively inflatable balloon having a forward end (distal end of 76, FIG. 4) and a rearward end (proximal end of 76, FIG. 4),
said rearward end of said balloon being located adjacent said distal end of said tube at a rearward balloon end mounting location (90) and said forward end of said balloon being located adjacent a distal end of said at least one elongate element at a forward balloon end mounting location (92),
thereby producing bowing of said at least one elongate element upon inflation of said balloon (FIGS. 2-4).
But fails to describe wherein at least part of the elongate element is extendable forwardly of a distal end of said tube.
However, it would have been obvious to one skilled in the art to provide the device within a further catheter, such that it is extendable out of the end of a tube so as to further protect elongate tube and because by nature, catheters are designed for insertion for further catheters within their lumens.

Johansen further fails to teach the limitation described by Kennedy wherein said balloon is configured such that when said at least one elongate element is in said fixed orientation and said balloon is in a deflated operative orientation, the distance between said rearward balloon end mounting location and said forward balloon end mounting location is greater than the distance between said rearward balloon end mounting location and said forward balloon end mounting location when said balloon is an inflated operative orientation (FIGS. 5; p4, in 3-12).

It would have been obvious to one skilled in the art to make the bending section a completely bowing section as described by Kennedy on the device of Johansen (as opposed to extension and bowing) because doing so would provide a tighter radius of curvature and because bowing of catheter ends is a known processes in the art of balloon catheters (Kennedy: p4, in 3-12).

-----Please See Continuation Sheet-----

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IL 03/00687

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Supplemental Box:-----

As per claim 20, Johansen and Kennedy describe the catheter according to claim 19, but fails to describe wherein the distance between said rearward balloon end mounting location and said forward balloon end mounting location is greater than the distance between said rearward balloon end mounting location and said forward balloon end mounting location when said balloon is an inflated operative orientation by at least 20%.

However, it would have been obvious to one skilled in the art to provide differences of 20% or more so as to increase the bending radius for increased applicability in tortuous vasculature through routine testing.

As per claim 21, Johansen and Kennedy describe the catheter according to claim 19 or claim 20, Johansen further describes and wherein said bowing of said elongate element is in a predetermined direction (col 5, ln 42-44; FIG. 4).

Claims 29 lacks an inventive step under PCT Article 33(3) as being obvious over Johansen in view of US 2006/0241345 A1 to Oishi et al. (hereinafter: Oishi).

As per claim 29, Johansen describes an enhanced flexibility auxiliary assembly (10, FIG. 3) for use with an catheter, the assembly comprising:

at least one flexible elongate element (14/64/62, FIG. 2; col 2, ln 20-25);

a flexible sleeve (14/64/62, FIG. 2; col 2, ln 20-25) having a first lumen for accommodating a distal portion of an catheter device (17, FIG. 1; col 2, ln 38-40); and

an inflatable balloon mounted onto said flexible sleeve (76, FIG. 4), said inflatable balloon, when in a non-inflated state, having a forwardly facing generally tapered end (92, FIG. 2) and a rearwardly facing generally tapered end (66, FIG. 2)

but fails to describe the device being an endoscope with a second lumen for accommodating said at least one flexible elongate element or wherein said forwardly facing generally tapered end having a slope which is less steep than a corresponding slope of said rearwardly facing generally tapered end.

However, Oishi describe an endoscope device with multiple lumens for a balloon device and extra endoscopic devices (para[0042]), where the balloon is configured such that said forwardly facing generally tapered end having a slope which is less steep than a corresponding slope of said rearwardly facing generally tapered end (FIG. 3).

It would have been obvious to one skilled in the art to employ an endoscope for the device as described by Oishi on the device of Johansen (in place of a plain catheter) so as to visualize the procedure, as well as to provide lumens for various tools and to provide a less tapered forward end in because doing so would provide a less traumatic device during insertion.

Claims 1-5, 10-14, 19-21 and 29 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of July 1, 2009, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at <http://www.wipo.int/pct/en/texts/index.htm>.

Effective July 1, 2009, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (e.g., CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

I. AIS PART 8 AND ANNEX C-BIS DELETED AS OF JULY 1, 2009

- A) Sequence-related tables cannot be filed as a separate part of the description or in text format. They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
 - on paper as part of an international application filed on paper.
- B) A *sequence listing forming part of an international application* may be provided either:
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
 - Annex C/ST.25 text format (preferred), or
 - PDF format; or
 - on paper as part of an international application filed on paper.
- C) A *sequence listing not forming part of the international application* (for search under PCT Rule 13ter) in Annex C/ST.25 text format
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
 - is required for search where the *sequence listing forming part of the international application* was filed in PDF
 - is required for search on physical medium (e.g., CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

- A) A sequence-related table must form an integral part of the international application and will incur FULL page fees with no upper limit.
- B) A *sequence listing forming part of an international application* filed:
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
 - on paper or in PDF format will incur FULL page fees with no upper limit.

III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE 13TER

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13ter. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at <http://www.wipo.int/pct/en/forms/index.htm>.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Volume I/A, Annexes B1 and B2).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, Volume I/A, paragraph 296).

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.